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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,201	05/15/2007	Jean-Pierre Sachetto	SACH3001/ESS	8441

23364 7590 02/18/2010

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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,201	SACHETTO ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-22 and 35-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-22 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-10, 13-22 and 35-41 are pending and the subject of this Office Action. Claims 38-41 were added on 05 January 2010.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' arguments filed on 05 January 2010 in response to the final rejection filed by this Office on 10 June 2009 have been fully considered, but they are not deemed to be persuasive. Rejections and objections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated and expounded upon, and they constitute the complete set presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13-22, and 35-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 13-17 of U.S. Patent No. 5,792,795 in view of U.S. Patent No. 4,935,243 (Col. 3, lines 20-46)[hereinafter referred to as "Borkan et al"] and in further view of U.S. Patent PreGrant Publication No. 2003/0064074 [hereinafter referred to as "Chang et al"].

The '795 patent contains a general disclosure of a soft gelatin capsule that encloses eicosapenta-5,8,11,14,17-enoic acid, docosahexa-4,7,10,13,16,19-enoic acid or mixture thereof, just as contemplated by the present invention. With regard to whether the capsule shell, it is

well-known in the art that both Type A and Type B gelatins and blends thereof can be used to obtain a gelatin shell with the requisite viscosity and bloom strength. See Borkan et al., Col. 4, lines 30-33.

Claim 15 teaches the limitation that the gelatin used comprises fish gelatin. Borkan does teach a capsule that can be formed from Type A and Type B gelatins and also and that "[t]ype A gelatin is derived ***mainly*** from porcine skin" (Emphasis added)(Col. 3, lines 24-33). More specifically, Borkan et al teach that "[g]elatin may also be derived from the skin of cold water fish" (Col. 3, lines 29-30). In stating that porcine is used "mainly" for Type A gelatin, one of ordinary skill in the art would know that other types of skin may be utilized to get Type A gelatin, too. Consistent with the teachings in Borkan, Chang et al teach that in extracting Type A gelatin, the process generally involves subjecting fresh or frozen porcine hides (Chang et al Page 2, Para. 12). However, fish gelatin is also processed as Type A gelatin (Page 2, Para. 15).

In light of the foregoing, it would be obvious to one of ordinary skill in the art to modify the more general teachings of the '795 by Borkan et al to conclude the use of Type A and Type B gelatins and blends thereof to be used to obtain a gelatin shell for a capsule enclosing eicosapenta-5,8,11,14,17-enoic acid, docosahexa-4,7,10,13,16,19-enoic acid or mixture thereof, just as contemplated by the present invention.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13-16, and 35-41 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as "Breivik et al"](the reference is being considered in its totality) in view of Borkan et al and in further view of U.S. Patent PreGrant Publication No. 2003/0064074 [hereinafter referred to as "Chang et al"].

The teachings of Breivik et al. and Borkan et al. from this Office's Actions of 28 January 2008, 09 October 2008, and 10 June 2009 as well as the reasoning association therewith, are incorporated herein by reference in their entirety.

Applicants argue that there is no disclosure in Breivik et al of the use of any particular gelatin and most particularly, the use of Type A gelatin. Applicants further argue that the "reference speculates that the EPA and the DHA formulation could be in the form of the free acid. However such an embodiment is not exemplified" (Page 7 of Applicants' remarks of 25 November 2008). However, in the same paragraph that Applicants, by their own admission state "BREVIK exemplifies a soft gelatin capsule ..." *Id.* Applicants go on further to say the "reference speculates that the EPA and the DHA formulation could be in the form of free acid." *Id.* It is important to note that Breivik is an issued U.S. patent. Therefore, the disclosures therein are presumed valid and therefore, Applicants' assertion that the "reference speculates" and arguments emanating therefore are but allegations lacking factual support.

Additionally, Applicants argue that by Borkan stating that gelatin may be of Type A, Type B or a mixture thereof that "BORKAN actually evidences the unexpected nature and nonobviousness of the claimed invention" (Page 7 of Applicants' remarks of 25 November 2008). This is unpersuasive. Applicants' claim set utilizes the open claim language, "comprising

Type A gelatin." The same permits the very teaching in Borkan, Type A, Type B and/or a blend of Type A and Type B.

Claim 15 teaches the limitation that the gelatin used comprises fish gelatin. Borkan does teach a capsule that can be formed from Type A and Type B gelatins and also and that "[t]ype A gelatin is derived ***mainly*** from porcine skin" (Emphasis added)(Col. 3, lines 24-33). More specifically, Borkan et al teach that "[g]elatin may also be derived from the skin of cold water fish" (Col. 3, lines 29-30). In stating that porcine is used "mainly" for Type A gelatin, one of ordinary skill in the art would know that other types of skin may be utilized to get Type A gelatin, too. Consistent with the teachings in Borkan, Chang et al teach that in extracting Type A gelatin, the process generally involves subjecting fresh or frozen porcine hides (Page 2, Para. 12). However, fish gelatin is also processed as Type A gelatin (Page 2, Para. 15).

With regard to claims 8-10 and 35-41, Applicants specify dosage ranges that vary between 100 mg and 2000 mg and temperatures at 40 degrees Celsius for storage and 37 degrees Celsius for disintegration. As a matter of law, "[g]enerally, differences in concentration or temperature [or time] will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)). The burden shifts to Applicant to show that the ranges contained in their invention are indeed critical.

With regard to Applicants' claims 3-5 and 7, Brevik et al teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein

(all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids (Abstract). As a result of this teaching, the instant claims fall within the purview of the prior art.

With regard to claim 16, the limitation requiring a single layer capsule, it is important to note that Borkan et al teach a "chewable, edible soft gelatin capsule which comprises ***a*** shell comprising … gelatin … said shell dispersible and soluble in the mouth of the user" (Emphasis added)(Abstract). A plain read of the language "a shell" suggests a single layer, thereby bringing claim 16 within the purview of the prior art.

Furthermore, gelatin types, between Type A and Type B are interchangeable and most often, plasticizers are added to produce soft gelatin that is chewable and the same has been known as early as the 1990s, based on the disclosures herein (Col. 3, lines 40-46). Applicant makes a claim, but provides no nexus. The mere statement that Borkan evidences the unexpected nature and nonobviousness of the claimed invention cannot be presupposed by teachings of two gelatin types only or mixtures thereof.

Applicants go on to state that one of skill in the art would lack motivation to combine and modify Breivik and Borkan to arrive at the instant invention stating in part as rationale that the primary difference between the different types is the manufacturing process. However, as noted by the Office pursuant to the teachings in Borkan et al, the formations are by the same processes and further, the use of the two types are known to be interchangeable.

Agreeably, the Examiner acknowledges the Patent Office's burden to consider objective indicia of nonobviousness when it is present and pursuant to Applicants' request, a more close review of Table 1 on page 10 was undertaken to ascertain whether indeed there were unexpected

results. A review of the same did not reveal conclusive data to support the Applicants' claim of unexpected results, most especially in analyzing data with storage temperatures at 25 degrees and 30 degrees.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to conclude that the making and administration of a soft gelatin capsule containing EPA and DHA would be effective in the treatment of hypertriglyceridaemia.

Claims 17-22 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as "Breivik et al"](the reference is being considered in its totality) in view of Borkan et al and in further view of U.S. Patent PreGrant Publication No. 2003/0161872 [hereinafter referred to as "Chen et al"].

The teachings of Breivik et al and Borkan et al, supra, and from previous Office Actions are incorporated herein by reference in their entirety.

Applicants, in claims 17-22, claim soft gelatin capsules with at least on enteric material integrated with the gelatin of the capsule wherein the said material is poly(ethylacrylate-methylmethacrylate). Chen et al teach a capsule shell that can be soft (Page 1, Para. 7) and comprise poly(ethylacrylate-methylmethacrylate)(Pages 1 and 2, Paras. 8 and 12), with an enteric coating layer on the capsule shell (Page 3, Para. 31). Chen et al also teach that the invention therein would be useful for the preparation of drugs for "enteric delivery (i.e., for drugs that are intended to be deliver [sic] to the duodenal and intestinal regions), because they resist to the acidic pH in the stomach" (Page 3, Para. 25).

One of ordinary skill in the art would be motivated to modify the combined teachings of Borkan et al and Breivik by the teachings in Chen et al to arrive at the instant invention due to the overlap in subject matter, most notably, soft capsule.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a soft shell gelatin capsule containing poly(ethylacrylate-methylmethacrylate) with an enteric coating.

Conclusion

No claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

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